REMARKS

The claims are 1-18. Claims 1-7, 9, 11-12, 16 and 17 have been amended to better define the invention. No new matter has been added. Favorable reconsideration thereof is respectfully requested.

Initially, the Examiner has objected to claims 1-6 for the use of the phrases "the, or each, reservoir" or "the, or each, hole or opening". As suggested by the Examiner those claims have been amended for purposes of clarification. Although not objected to, a similar change was made to claim 7.

I. Response to Rejections Under 35 U.S.C. §112

The Examiner has asserted that the specification does not support the utilization of pore forming excipients in the reservoir. The Examiner has also rejected claims 14 and 15 as being non-enabled for the same reason. Applicants respectfully disagree. As noted by the Examiner, Example 3 discloses the use of a pore-forming excipient, hydroxyethyl cellulose. The Examiner discounts this disclosure because the rings of Example 3 are created by using projections or bore drilling to create pores. While this is true, it is not relevant to the use of a pore forming excipient. The projections or bore drillings are used to make holes or openings that extend through the sheath to or into the reservoir. This is different than the creation of "pores" within the reservoir as disclosed in Example 3. However, to move this case forward and obviate this rejection, Applicants have amended the specification at page 19, line 5 by adding the sentence: "These excipients that further enhance the rate of drug release are referred to herein as pore-forming excipients." Support may be found in claims 14 and 15.

Claims 4, 7, 9-11 and 14-16 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. The Examiner believed it was unclear how two holes create a slit. Claim 4 has been amended to make clear that the hole or opening is in the shape of a slit.

Support may be found, for example, at page 4, lines 4-11 of the published international application.

The Examiner also found unclear the phrase of claim 7 that "the, or each, hole extends substantially radially, inwardly or outwardly, through the sheath." The claim has been amended to make clear that device is a ring and that hole extends substantially radially through the sheath at the inner circumference of the ring or at the outer circumference of the ring. Support for this claim change is found throughout the specification, for example at page 5, lines 1-5 and Figure 1.

The phrase "said holes" in claim 9 is alleged not to have antecedent basis. The claim has been amended to recite that "at least one hole or opening is provided at each terminal end of the rod."

The Examiner requests clarification of the phrase "right circular cylinder" used in claim 10. The Examiner is referred to page 15, lines 28-31 for a definition of a right cyclinder, i.e. a cylinder whose bases are normal to the generatrix.

Claim 11 has been amended to recite "further holes or openings" since it is clear that a slit is a type of hole or opening.

With respect to claim 14, the Examiner requests clarification regarding the meaning of "pore-forming excipient". Applicants submit that this is simply an excipient that assists in creating pores within the reservoir so as to enhance the rate of drug release. See page 18, line 27 to page 19, line 5 of the published international application.

Claim 16 has been amended to make clear that the sheath contains an additional pharmacologically active agent, i.e., one different than that contained in the reservoir.

II. Response to Rejections Under 35 U.S.C. §102

A. The Examiner alleges that the subject-matter of Claims 1-3, 6-8, 13, 17 and 18 lack novelty over Graham (US 4,973,304). Applicants respectfully traverse this rejection.

The Graham device, as illustrated in its Figure 3, is a device for insertion into the vagina, comprising a tube constrained in the form of a toroid and having a plurality of ports 13. Sections 15 of hydrogel material are placed inside the tube such that this hydrogel material extends across the ports 13. A contraceptive **solution** (emphasis added) is provided within the device. The contraceptive material then diffuses out through the hydrogel material and across the ports 13 to release the contraceptive material.

The Graham devices require the presence, within the cavity, of hydrogel material that, in the swollen condition, is not contiguous with the entire cavity wall but that covers the port or ports in the wall, so that the active substance within the cavity is released by diffusion through the swollen hydrogel layer. To this end, the active substance within the cavity is a solution (see column 3, line 35; column 3, lines 40 and 41 and 46; column 4, lines 37-55; column 5, lines 51-54; column 6, lines 47 and 60, referring to the intravaginal delivery device of Figure 3; column 7, lines 22 and 23; claims 10 and 12).

In the use of the Graham device, the drug solution must diffuse through the hydrogel material. As the Examiner will appreciate, hydrogels absorb water and are, by definition, hydrophilic in their nature. In contrast, the intravaginal drug delivery devices of the present invention require that the carrier system be a hydrophobic elastomeric polymer.

The Graham device does not disclose the use of drugs dispersed in a hydrophobic elastomeric polymer. Accordingly, Applicants submit that the claims as amended are not disclosed or suggested by Graham.

B. The Examiner alleges that the subject-matter of Claims 1, 2, 9 and 10 lack novelty over Drury (US 6,242, 972). Applicants respectfully traverse this rejection.

US Patent No. 6,264,972 (Drury) discloses a tampon. One of the objects of the Drury invention (see column 2, lines 60-63) is to provide a tampon that exhibits better fluid retention with less leakage than prior art tampons. At column 3, lines 34-35, it is taught that the inner center 14 is a soft porous fluid absorber. At column 3, lines 46-47, it is taught that the carrier material, polyvinyl acetyl, has been selected because of its adsorbability of fluids. Further on, at column 3, line 56, it is taught that the tampon wicks up fluid. At column 4, lines 26-28, it is taught that the inner center 14 is an open-celled sponge with instantaneous fluid wicking, an absorbtive capacity of up to 27 times its weight in fluids and a retained fluid capacity of up to 16 times its own weight in fluids. It will, of course, be appreciated that, in order to fulfil the object of the invention in terms of fluid retention, the carrier material must be capable of attracting and absorbing water, in other words, the carrier material must be hydrophilic.

The claims of the present application have been amended to require that the carrier system be a hydrophobic elastomeric polymer. Since Drury does not disclose any hydrophobic elastomeric polymers, the amended claims are not disclosed or suggested by Drury.

C. The Examiner alleges that the subject-matter of Claims 1 - 3 and 14 lack novelty over Waterbury (US 3,521,637). Applicants respectfully traverse this rejection.

US Patent No. 3,521,637 (Waterbury) concerns tampons or similar sanitary napkins. At column 2, lines 54-61, it is taught that vaginal tampons are usually made of absorbent fibers designed to provide the required absorbing capacity. At column 3, lines 4-5, it is taught that cotton and rayon are particularly suitable because of their highly absorbent properties. Further on, at column 3, lines 10 and 11, it is taught that such cellulose materials

have the required absorbent capacities. At column 4, lines 6-13, it is taught that conventional vaginal tampons are capable of absorbing 5-10 ml of fluid. Waterbury's Claims 1 and 2 are directed to compressed vaginal tampons or sanitary napkins comprising an outer wrapper and a matrix of compressed absorbent fibres within that outer wrapper. Waterbury concerns itself with tampons having a required fluid absorption, in other words, the matrix tampon must be capable of attracting and absorbing water and is, therefore, hydrophilic. Waterbury does not disclose a carrier system that is required to be hydrophobic and elastomeric. Accordingly, the claims of the present invention are not disclosed or suggested by Waterbury.

III. Response to Rejections Under 35 U.S.C. §103

A. The Examiner alleges that the subject-matter of Claims 5, 11 and 12 are obvious over Graham. Applicants respectfully traverse this rejection.

Figure 3 of Graham illustrates a toroidal device formed of a tube of elastomer material 11 containing a contraceptive **solution** (emphasis added) and having a number of ports 13, with cylindrical sections of hydrogel material that are not contiguous with the entire cavity wall but are discontinuously positioned across the ports 13. In order to prevent the contraceptive solution from simply leaking out of the device, the device of Figure 3 requires that the hydrogel material 11, at least in use, be in this swollen state. This is achieved by using a carrier material that can attract water, or is hydrophilic. If a hydrophobic elastomeric material were used in its place and not being contiguous with the entire cavity wall, the hydrophobic material would not swell up and the contraceptive solution would simply drain out of the ports. There is, therefore, no incentive to the person of ordinary skill in the art to even consider replacing the required hydrogel carrier material of Graham in order to arrive at the presently claimed invention.

The devices of the present invention permit sustained release of drugs over up to 14 days (see Examples 1-4 and accompanying Figures 2-5). Such sustained release is permitted by dispersing the drug(s) in a hydrophobic elastomeric polymer, as is required by the claims of the present application.

Applicants submit that the claims as amended are clearly not suggested by the disclosure of Graham.

B. The Examiner alleges that the subject-matter of Claims 11 and 12 and Claims 14 and 15 lack inventive step over Drury in view of Graham. The Examiner also alleges that the subject-matter of Claims 15 and 16 are obvious over Waterbury, or over Waterbury in view of Fuchs (US 4,136,162), respectively. Applicants respectfully traverse these rejections.

Each of Drury and Waterbury are concerned with tampons, an essential property of which is their ability to absorb fluids. Neither of Drury or Waterbury suggests the replacement of their respective carrier materials with a hydrophobic elastomeric polymer and a skilled man would not consider such a substitution, since a hydrophobic elastomeric polymer would repel water and the tampons would no longer operate in the desired manner.

US Patent No. 4,136,162 (Fuchs) concerns unit dosage forms prepared by drawing mixtures of drug and carrier into a film that can be cut to the desired dosage content. The Examiner has drawn attention to the passage at column 4, lines 27-58 as allegedly disclosing a perforated film. Closer review of the passage in question suggests that this is merely describing the ability to prepare different films from a single sheet. Once the wet sheet has been drawn out, individual unit dosages are separated from one another, by separating them at the perforations. There is no disclosure or suggestion in Fuchs that an individual unit dosage film would be perforated. The passage in question ends by stating that the films can be rolled about a

commercial tampon. Example 16 exemplifies a film for intravaginal application that is prepared according to Example 11. Example 16 concludes by stating that one unit of that film is either rolled around an ordinary commercial tampon or is itself rolled to form a narrow tube. Again, neither Example 11 nor Example 16 discloses or suggests that, within an individual unit dosage, the film might be perforated. In any event, and not withstanding the foregoing, the only disclosure or suggestion in Fuchs is to roll the film about an ordinary commercial tampon. Once again, tampons have a required fluid absorption and, as such, are hydrophilic. It is respectfully submitted that there is no motivation or guidance that would have led a person of ordinary skill in the art to replace the carrier material with a hydrophobic carrier material with a reasonable expectation of successfully obtaining the present claimed invention.

Wherefore, none of the art of record, whether taken alone or together, discloses or suggests the presently claimed invention. Accordingly, it is respectfully requested that the claim be allowed and the case passed to issue.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

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